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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/927,091	08/09/2001	Ann Killary	UTSC:651US	4158

7590 09/24/2004
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EXAMINER

WHITEMAN, BRIAN A

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 09/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,091	KILLARY ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7,17-97,100 and 101 is/are pending in the application.
- 4a) Of the above claim(s) 18-23,34-43,45-96 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-6,24-33 and 44 is/are allowed.
- 6) ☒ Claim(s) 7,17,97,101-102 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Non-Final Rejection

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/04 has been entered.

Claims 1-7, 17-97, and 101-102 are pending.

Election/Restrictions

Claims 18-23, 34-43, and 45-96 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 9/22/03.

Information Disclosure Statement

As stated in the last office action mailed on 5/21/04, the IDS filed on 10/7/02 indicated that there are 3 pages. The examiner only signed page 1 of the IDS filed on 10/7/02 because pages 2 and 3 were not available for the examiner to sign. If the applicants want the patents and/or articles on pages 2 and 3 from the IDS to be considered and/or initialed by the examiner, then the applicants should submit pages 2 and 3 of the IDS in response to the instant office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 17, and 101-102 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon further consideration of the amendment filed on 3/26/04, applicants have not pointed out where the limitation 'an isolated and purified nucleic acid of about 2500 to about 5000 base pairs' for claim 7 is supported by the specification and there does not appear to be a written description of the claim limitation 'an isolated and purified nucleic acid of about 2500 to about 5000 base pairs' in the application as filed. See MPEP § 2163.06.

In addition, the currently amended claim 7, claim 17 (dependent on claim 7) and newly filed claims 101-102 are not supported by the as-filed specification. There appears to be no written description in the application as filed for an isolated and purified nucleic acid of about 2500 to about 5000 base pairs comprising from about 18 (claim 7), 20 (claim 101), 25 (claim 102) or 3500 (claim 17) contiguous base pairs of SEQ ID NO: 3, or the complement thereof. Page 23 in the instant specification is cited by applicants for support of the amended claim and new claims, but this page does not disclose the claimed isolated nucleic acid as amended or

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newly filed. On page 23, applicants contemplate: "exemplary oligonucleotides of 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 25, 30, 35, 40, 45, 50, 55, 60, 65, 70, 75, 80, 85, 90, 95, 100 or more base pairs will be used, although others are contemplated. Longer polynucleotides encoding 250, 500, 1000, 1212, 1500, 2000, 2500, 3000 or longer are contemplated as well."

The page provides support for oligonucleotides of certain length, but does not provide support for an isolated and purified nucleic acid of about 2500 to 5000 base pairs comprising about 18, 20, 25, or 3,500 contiguous base pairs of SEQ ID NO: 3. Applicants further cite the limitation '18 contiguous base pairs of SEQ ID NO: 3' in amended claim 7 for support of the amended claim and new claims. Amended claim 7 does not provide written description for the amended and new claims because, as stated above, the limitation 'about 2500 to 5000 base pairs' does not have support in the specification as filed. Therefore, in view of the proposed support cited by applicants for the amended claim and new claims cited, the specification does not specifically disclose an isolated nucleic acid of about 2,500 to about 5,000 base pairs comprising from about 18, 20, 25, or 3,500 contiguous base pairs of SEQ ID NO: 3, or the complement thereof.

"It is not sufficient for purposes of the written description requirement of Section 112 that the disclosure, when combined with the knowledge in the art, would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose."

Lockwood v. American Airlines Inc., 41 USPQ2d 1961, 1966 (CAFC 1997).

It is apparent that the applicants at the time the invention was made did not intend or contemplate the isolated and purified nucleic acid cited in the claims and claims dependent therefrom as part of the disclosure of their invention. There is no evidence in the specification that the applicants

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were in possession of the claimed nucleic acid as set forth in the claims, as it is now claimed, at the time the application was filed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Upon further consideration and in view of the lack of a definition for the term “high stringency conditions” in the instant specification, the rejection of claim 97 as being anticipated by Waterson under 102(a) in the office action mailed on 12/16/03 is reinstated.

Claim 97 is rejected under 35 U.S.C. 102(a) as being anticipated by Waterson (GenBank Accession No. AC022262, US National Library of Medicine, Bethesda, MD, July 2000, accessed by PTO on 10/23/03, cited on a previous PTO-892). Waterson anticipates claim 97 because Waterson teaches an isolated nucleic acid with Accession No. AC022262 has nucleotides 17,334-18,641 that are 100% identical to nucleotides 2,500-3,807 of SEQ ID NO: 3.

The nucleic acid taught by Waterson would hybridize under high stringency conditions because the specification does not define the term “high stringency conditions” and the sequence is 100% identical to a DNA segment comprising about 2500 to about 3807 of SEQ ID NO: 3.

Applicant's arguments filed 3/26/04 have been fully considered but they are not persuasive because the limitation 'about 2500 to 3826 bases of SEQ ID NO: 3' in the amended claim does not overcome the prior art rejection because the isolated nucleic acid taught by Waterson still anticipates the nucleic acid in claim 97.

Claim 97 is rejected under 35 U.S.C. 102(b) as being anticipated by Hillier et al. (GenBank Accession No. R71654, US National Library of Medicine, Bethesda, MD, June 1995, accessed by PTO on 9/21/04). Hillier anticipates claim 97 because Hillier teaches a nucleotide sequences with 100% similarity to 918-1295 of SEQ ID NO: 3. See nucleotides 391-14 of R71654.

The sequence taught by Hillier would hybridize under high stringency conditions because the specification does not define the term "high stringency conditions" and the sequence is 100% identical to a DNA segment comprising nucleotides 918-1295 of SEQ ID NO: 3.

Claims 7 and 101 are rejected under 35 U.S.C. 102(e) as being anticipated by Shatkin et al. (US 6,312,926).

Shatkin teaches an isolated nucleotide sequence (SEQ ID NO: 1) having 4,160 base pairs having at least 20 contiguous base pairs of applicants' SEQ ID NO: 3. See nucleotides 4136-4154 of SEQ ID NO: 1 in '926.

Claims 7, 101 and 102 are rejected under 35 U.S.C. 102(b) as being anticipated by Jacobs et al. (WO 98/42739). Jacobs teaches an isolated nucleotide sequence having 2,522 base pairs

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having at least 25 contiguous base pairs of applicants SEQ ID NO: 3 (page 76). See nucleotides 2519-2495 of SEQ ID NO: 7 in '739.

Conclusion

Claims 1-6, 24-33, and 44 are in condition for allowance because the claims are free of the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (571) 272-0764. The examiner can normally be reached on Monday through Friday from 7:00 to 4:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, SPE - Art Unit 1635, can be reached at (571) 272-0760.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system

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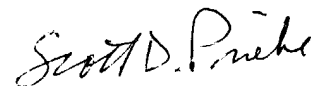
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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Brian Whiteman
Patent Examiner, Group 1635

A handwritten signature in black ink, reading "Scott D. Pribe". The signature is written in a cursive, flowing style.

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER